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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|----------------------------|----------------------|---------------------|------------------|
| 10/582,621 | 06/12/2006 | Michele Pallaoro | ITR0053YP | 4827 |
| MERCK AND | 7590 06/27/200 CO., INC | EXAMINER | | |
| P O BOX 2000 | | | MARVICH, MARIA | |
| RAHWAY, NJ 07065-0907 | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/27/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | |
|--|---|------------------------|--|--|--|
| Office Action Community | 10/582,621 | PALLAORO ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | MARIA B. MARVICH | 1633 | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | correspondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>12 Ju</u> | une 2006 | | | | |
| | s action is non-final. | | | | |
| <i>i</i> | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| ,— | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | |
| Disposition of Claims | | | | | |
| • | | | | | |
| 4) Claim(s) <u>1-8 and 10-22</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| <u> </u> | | | | | |
| 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. | | | | | |
| 7) Claim(s) is/are rejected to. | | | | | |
| 8) Claim(s) 1-8 and 10-22 are subject to restriction | on and/or election requirement | | | | |
| o) Claim(s) 1-0 and 10-22 are subject to restricted | on and/or election requirement. | | | | |
| Application Papers | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D: 5) Notice of Informal F 6) Other: | ate | | | |

DETAILED ACTION

Claims 1-8 and 10-22 are pending in this application and subject to the following restriction. It is noted in the amendment that claims 1, 12-16 and 20-22 indicate that they are "currently amended". However, none of the claims have markings indicative of amendment such as strikethrough for deletions and underlining for insertions. For compact prosecution, the amendment has been considered. However, an amendment in response to this restriction should follow 37 CR 1.121.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8 and 10-12, drawn to a method of identifying an analyte comprising providing a cell comprising a reporter gene operably linked to a regulatory region responsive to Apidicin, Trichostatin A, sodium butyrate, SAHA and MS27-275.

Group II, claims 1-8 and 10-12, drawn to a cell comprising a reporter gene operably linked to a regulatory region responsive to Apidicin, Trichostatin A, sodium butyrate, SAHA and MS27-275.

The inventions listed as Group I-II do not relate to a single general inventive concept because they lack the same or corresponding technical feature. A cell comprising a reporter gene operably linked to a regulatory sequence responsive to Apidicin, Trichostatin A, sodium butyrate, SAHA and MS27-275 is shown by Feinstein

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et al (see figure 3), to lack novelty of inventive step and does not make a contribution over the prior art. Hence, the claims lack unity of invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be

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amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call

Maria B Marvich, PhD Examiner Art Unit 1633

/Maria B Marvich, PhD/ Primary Examiner, Art Unit 1633

800-786-9199 (IN USA OR CANADA) or 571-272-1000.